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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,843	04/15/2004	Robert T. Lyons	17684 (AP)	2070

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ALLERGAN, INC.
2525 DUPONT DRIVE, T2-7H
IRVINE, CA 92612-1599

EXAMINER	
FAY, ZOHREH A	
ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/826,843	LYONS ET AL.	
	Examiner	Art Unit	
	Zohreh A. Fay	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-27 are presented for examination.

The amendments and remarks filed on September 11, 2006 have been received and entered.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some agents, does not reasonably provide enablement for the broad phrase of "an agent". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The factors to be considered whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir.1988). Among these factors are:

1) The nature of the invention:

2) The state of the prior art:

3) The relative skill of those in the art:

4) The predictability or unpredictability of the art:

The unpredictability of pharmaceutical and chemical art is high.

5) The breath of the claims:

The claims are very broad and encompass a method of delivery of an agent in combination with certain cyclodextrin derivatives, a pharmaceutical product

comprising an agent and certain cyclodextrin derivatives and a composition of an agent and certain cyclodextrin derivatives for delivery to the eye.

6) The amount of direction or guidance provided:

Applicant's specification provides guidance for and it is only enabled for use of certain agents in combination with certain cyclodextrin derivatives. In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in applicant's specification either by the enumeration of a sufficient number of the members of the group or by other appropriate language, that the chemicals and chemical combinations included in the claims are capable of accomplishing the desired results." Applicant's specification does not set forth a representative number of examples of an agent in combination with cyclodextrin capable of performing the claimed function.

7) The presence or absence of working examples;

The examples in applicant's specification are drawn to the effect of one agent in combination with cyclodextrin derivatives for delivery to the eye.

8) The quantity of experimentation necessary;

Since compound structure and activity for such pharmaceutical use must be determined from case to case by painstaking experimental study, one of ordinary skill in the art would be burdened with undue experimentation to determine all agents in combination with cyclodextrin derivatives being capable of delivery to the eye.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-27 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 02/089815. The WO patent teaches the use prednisolone acetate in combination with the claimed cyclodextrins and HPMC in an ophthalmic formulation for the delivery to the eye. See page 10, lines 8-13, page 12 lines 11-26 and the table in page 14. The above teachings read on the claimed invention.

Claims 1-15 and 19-27 are rejected under 35 U.S.C. 102 (b) as being anticipated by Guy (U.S. Patent 5576,311) for the reasons set forth on page 2 of the office action of June 29, 2006.

Claims 16-18 are rejected under 35 U.S.C. 103 as being unpatentable over Guy (U.S. Patent 5,576,311) in view of Loftsson (U.S. Patent 5,576,311) for the reasons set forth on pages 3 and 4 of the office action of June 29, 2006.

Applicant's arguments and remarks regarding the 102 (b) have been carefully considered, but are not deemed to be persuasive. Applicant in his remarks argues that Guy does not teach "delivering a therapeutically effective amount of an active agent to a structure or combination of structure of the eye which includes vitreous humor or structures posterior to the vitreous." The arguments are not well taken. Guy by treating an ophthalmic condition clearly delivers the claimed composition to a structure of an eye. Although there are some ophthalmic disorders, which may be treated without

carrying out the claimed method, there are also numerous ophthalmic disorders, which can be treated by carrying out the claimed method. Applicant also argues that the claimed product is a solution and not a suspension. Applicant refers to the solubilization or complexation of solution in comparison with a suspension. The arguments are not well taken. There is nothing in the applicant's specification or claims directed to solubilization or complexation of drugs used in combination with cyclodextrin. The arguments regarding the administration of a drug from a container with written instruction are not also well taken. The dispense of a drug from a container is considered to be within the skill of the artisan. The printed instruction does not introduce a patentable weight to a claimed product. Applicant's attention is directed to In re Ngai, F.3d, 2004 WL 1068957 (Fed. Cir 1983). Applicant's arguments regarding the obviousness rejection have also been carefully considered, but are not deemed to be persuasive. Applicant refers to the therapeutically effective amount of the claimed composition in comparison with the prior art. Applicant is reminded that the instant specification only describes concentrations of prednisolone and not other active ingredients. Therefore, the determination of optimum proportions or amounts are considered to be within the skill of the artisan in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh A. Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Z.F

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600

Zohreh Fay